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JFCT-1-03 (CIP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|---|---|
| APPLICANT(S): | V. M. Chopdekar et al. | : | Examiner: Shahnam J. Sharareh |
| SERIAL NO. : | 10/734,460 | : | Art Unit: 1617 |
| FILED : | December 12, 2003 | : | |
| FOR : | OPIOID TANNATE COMPOSITIONS | : | |

**SECOND PETITION FOR SUSPENSION OF ACTION BY THE OFFICE**
**[37 C.F.R. § 1.103(a)]**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicants respectfully requests the Office to **again** suspend action on this application for the reasons presented below. This **Second** Petition is accompanied by a showing of good and sufficient cause for the suspension of action as supported by Exhibits AA - CC attached hereto.

This Petition is also accompanied by a Credit Card Payment in the amount of $200.

In the Office Action mailed June 6, 2006, claims 1-3 and 8-9 were rejected under 35 U.S.C. § 102 as being anticipated by British Patent 894,609 ("GB '609"). Claims 1-10 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer US Patent 5,869,498 in view of GB'609. In order to establish patentability over the cited references, applicants have initiated a program to compare tannates of morphine and codeine prepared by the method described in GB'609 with the tannates of morphine and codeine prepared by the method described in the instant patent application. It is believed that there will be significant differences in the physical and chemical properties of the two types of tannates. However, applicants cannot respond to the rejections under 35 U.S.C. § 102/103(a) since applicants must receive permission from the Drug Enforcement Agency to acquire research quantities of morphine and codeine which are controlled substances.

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A prior Petition for Suspension was submitted on September 19, 2006. Such prior Petition for Suspension was granted pursuant to the Office Action mailed October 4, 2006.

The applicants have in fact received permission from the Drug Enforcement Agency in the form of quotas to receive up to 0.05 K of both morphine and codeine. In January 2007, applicants were able to locate commercial sources for both morphine and codeine, but the DEA-approved quotas expired on December 31, 2006.

Applicants have requested an extension from the Drug Enforcement Agency. However, permission to acquire the quotas of 0.05 K of both morphine and codeine must await publication in the *Federal Register* of the granting of such extension.

As soon as the Drug Enforcement Agency's approval has become final, applicants will acquire the quotas of the morphine and the codeine and promptly commence the comparative work in the laboratory to demonstrate that the opioid tannates, i.e., morphine tannate and codeine tannate, of the invention differ from the morphine tannate and the codeine tannate prepared by the method described in the cited prior art, i.e., GB'609.

It is anticipated that the Drug Enforcement Agency's approval will become final by the end of April, 2007. Thereafter, the permitted quotas of the morphine and codeine will be ordered by the applicants and should be received by June, 2007. The comparative laboratory work should then be completed by the end of August, 2007 and a response to the office action of June 6, 2006 will be made within two weeks thereafter. Thus, the granting of an additional suspension of six (6) months should be sufficient.

The following exhibits are attached in support of this Petition:

Exhibit AA are copies of letters sent to the DEA dated September 7, 2006 establishing the need to obtain research quantities of Morphine Sulfate and Codeine Sulfate.

Exhibit BB consists of two (2) pages of emails to and from Mary Ciamaga (Customer/Vendor Relations Manage fo the Assignee: JFC Technologies) and the DEA regarding information for renewal applications as a Manufacturer and an Importer. The information in support of renewal applications RJ0311314 Importer and RJ0158318, Manufacturer was emailed to the DEA on November 16, 2006. The DEA email of February 8, 2007 indicated that the relevant notices are in the chain for a decisions for consideration for approval for publication in the Federal Register.

Exhibit CC is a photocopy of a letter from the DEA dated February 26, 2007 in which the DEA has established procurement quotas for morphine and codeine in the amount of 0.05 K for each substance.

It is respectfully submitted that the foregoing showing supports the granting of this Second Petition for Suspension If further information is required, please contact the undersigned.

Respectfully submitted,

Jack Matalon
Attorney for Applicants
Reg. No. 22,441

Law Offices of Jack Matalon
32 Shelley Rd.
Springfield, NJ 07081-2529

Tel: (973) 467-5626
Fax: (973)-921-0817

**CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 CFR § 1.8**

I hereby certify that this correspondence consisting of a total of 10 pages is being sent by facsimile transmission to the Examiner at (571) 273-8300 on March 21, 2007.

Jack Matalon

EXHIBIT AA 2

# JFC Technologies

"COMMON SENSE AND PLAIN DEALING"

September 7, 2006

Protocol for Morphine Tannate:
To obtain patent support information, we will be attempting to prepare a Tannate salt of morphine. We would need to use Morphine sulfate to prepare the Tannate.

Morphine Sulfate = 25 grams
1 gram for assay. 24 grams will be converted to morphine base by reaction with dilute NaOH.
The yield of morphine base (95%) = $\frac{24 \times 570.66}{758.33} \times 0.95 = 17.16$ grams of morphine base
2.16 grams for assay/retain sample.

(1) Replicate patent example :
To 7 grams of morphine base + 70 cc of Isopropyl Alcohol, add 10.5 grams of tannic acid in 35cc of warm alcohol.
Yield = 13.5 grams of Morphine Tannate

(2) JFC Technologies procedure:
React 7 grams of morphine base (0.02453 moles) 8.3 grams of tannic acid
Yield = 14.54 grams (at 95% yield) of Morphine Tannate.

Characterize Morphine Tannate from steps (1) and (2) above by % base assay, FTIR and reactivity test.

100 West Main Street ▲ PO Box 669 ▲ Bound Brook, New Jersey 08805 USA
Tel (732) 469-7760 ▲ Fax (732) 469-3666
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S.N. 10/734,460

3

EXHIBIT AA

# JFC Technologies

"COMMON SENSE AND PLAIN DEALING"

September 7, 2006

Protocol for Codeine Tannate:
To obtain patent support information, we will be attempting to prepare a Tannate salt of codeine. We would need to use Codeine sulfate to prepare the Tannate.

Codeine Sulfate = 25 grams
Note: Patent example uses codeine sulfate as reactant and not as a base.

(1) Replicate patent example :
12 grams of codeine sulfate + 120cc of methyl alcohol + 30 cc of 1 N NaOH
To slurry produced from above, add 12 grams of tannic acid in 120cc of methyl alcohol.
Yield = 9 grams of Codeine Tannate

(2) JFC Technologies procedure:
Convert 12 grams of codeine sulfate to codeine base by reaction with dilute NaOH.
The yield of codeine base (95%) = $\frac{12 \times 598.72}{750.86} \times 0.95 = 9.1$ grams of codeine base
Use 1.1 grams of codeine base for assay and characterization.
8 grams of base for synthesizing Tannate.
React 8 grams of codeine base with 9.1 grams of tannic acid (5:1 mole ratio)
Yield = 16.25 grams (at 95% yield) of Codeine Tannate.

(3) Characterize Codeine Tannate from steps (1) and (2) above by % base assay, FTIR and reactivity test.

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submitted to the front office for consideration for approval for publication in the Federal Register as Notices of Registration.

*James "Jim" Arnold*
*Staff Coordinator/ODEG*
*Regulatory Control Unit*
*Office of Diversion Control*
*DEA Headquarters*
*202-353-1414 (Telephone)*
*202-307-4905 (Fax)*

*e-mail: James.A.Arnold@usdoj.gov*



-----Original Message-----
**From:** Ciamaga, Mary [mailto:CiamagaM@JFCTechnologies.com]
**Sent:** Tuesday, December 05, 2006 11:17 AM
**To:** Arnold, James A.
**Subject:** RE: Request for Information on Renewals, Importer& Manufacturer

Dear Mr. Arnold,
On November 16, 2006, we e-mailed the information requested below. What is the current status of our renewal applications (RJ0311314, Importer and RJ0158318, Manufacturer).
Thank you,
Mary

-----Original Message-----
**From:** Arnold, James A. [mailto:James.A.Arnold@usdoj.gov]
**Sent:** Wednesday, November 08, 2006 9:21 AM
**To:** Ciamaga, Mary
**Cc:** Baker, Susan D.; Brown, Marquita L
**Subject:** Request for Information on Renewals, Importer& Manufacturer

Mary:
In reference to your renewal applications as a Manufacturer and an Importer, please answer the attached questions for each and every drug code requested by your company and return them to me by E-mail as soon as possible.

Thank you for your time and effort in this matter. We are looking forward to your reply.

<<IMPORTER QUESTIONS.doc>> <<BULK MANUFACTURE QUESTIONS.doc>>

*James "Jim" Arnold*
*Staff Coordinator/ODEG*
*Regulatory Control Unit*
*Office of Diversion Control*
*DEA Headquarters*
*202-353-1414 (Telephone)*
*202-307-4905 (Fax)*
*e-mail: James.A.Arnold@usdoj.gov*

**EXHIBIT BB**

**Ciamaga, Mary**

**From:** Arnold, James A. [James.A.Arnold@usdoj.gov]
**Sent:** Thursday, February 08, 2007 8:09 AM
**To:** Ciamaga, Mary
**Cc:** Brown, Marquita L
**Subject:** RE: Request for Information on Renewals, Importer& Manufacturer



Mary:

These notices are in the chain for a decision for consideration for approval for publication in the Federal Register.

*James "Jim" Arnold*
*Staff Coordinator/ODEG*
*Regulatory Control Unit*
*Office of Diversion Control*
*DEA Headquarters*
*202-353-1414 (Telephone)*
*202-307-4905 (Fax)*

*e-mail: James.A.Arnold@usdoj.gov*



-----Original Message-----
**From:** Ciamaga, Mary [mailto:CiamagaM@JFCTechnologies.com]
**Sent:** Wednesday, February 07, 2007 2:58 PM
**To:** Arnold, James A.
**Subject:** RE: Request for Information on Renewals, Importer& Manufacturer

James,
What is the status of our renewals (RJ0311314, Importer and RJ0158318, Manufacturer)? The comment period for the importer registration was over as of January 2, 2007 and for the manufacturer as of January 30, 2007. Any information would be appreciated.
Thank you,
Mary Ciamaga
JFC Technologies, LLC

-----Original Message-----
**From:** Arnold, James A. [mailto:James.A.Arnold@usdoj.gov]
**Sent:** Tuesday, December 05, 2006 11:46 AM
**To:** Ciamaga, Mary
**Cc:** Baker, Susan D.; Brown, Marquita L
**Subject:** RE: Request for Information on Renewals, Importer& Manufacturer

The NOA's were published on December 1, 2006. There is now a thirty (30) day Comment & Objection Period for the Importer ((21 CFR 1301.34) and a sixty (60) day Comment & Objection Period for the Manufacturer (21 CFR 1301.33). As soon as the waiting periods are over, the applications will be

EXHIBIT BB

# JFC Technologies

"COMMON SENSE AND PLAIN DEALING"

To: Dr. Christine A. Sannerud, PhD, Chief
DEA HQS
Drug & Chemical Evaluation Section
2401 Jefferson Davis Highway
Alexandria, Virginia 22301

Date: November 16, 2006

Dear Dr. Sannerud,

We are re-submitting applications for procurement quotas for codeine and morphine. (as per your letter of 9/19/06), since the drug codes in question have been added to our DEA registration.
Since it is so late in the year, and the applications had been for 2006, we have also enclosed applications for 2007. If we do not receive the procurement quota for 2006 by Dec. 11th, we will not have enough time to procure the items before the end of the year. In that case, we would prefer to get the quotas for 2007.
Please call or e-mail if you have any questions.

Best regards,

Mary Ciamaga
Customer/Vendor Relations Manager
(732) 469-7760 ext. 12
ciamagam@jfctechnologies.com

Enclosures:
Letter from Dr.Sannerud dated Sept. 19, 2006
2006 procurement quota for codeine with protocol
2006 procurement quota for morphine with protocol
2007 procurement quota for codeine with protocol
2007 procurement quota for morphine with protocol

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EXHIBIT CC

**U.S. Department of Justice**
Drug Enforcement Administration

*www.dea.gov*

Washington, D.C. 20537

FEB 2 6 2007

Ms. Mary Ciamaga
Customer/Vendor Manager
JFC Technologies, LLC
P.O. Box 669
100 West Main Street
Bound Brook, New Jersey 08805

Dear Ms. Ciamaga:

This is in response to your correspondence dated February 8, 2007, in which you requested 2007 procurement quota(s) under your manufacturer registration (DEA #RJ0158318) for your facility.

Based on the information provided to this office, please be advised that the Drug Enforcement Administration (DEA) establishes your 2007 procurement quota(s), expressed in kilograms of anhydrous base, as follows:

| DEA Drug Code No. | Name of Drug | Quantity in Kilograms |
|---|---|---|
| 9050 | codeine | 0.050 |
| 9300 | morphine | 0.050 |

During the 2007 calendar year, requests for adjustments may be made at any time provided that accompanying data to justify an adjustment is submitted. Additionally, this office should be notified in writing concerning any 2007 product development requirements as early as possible. This will allow the DEA to consider these requirements with the revised 2007 aggregate production quotas.

You are reminded that you may only acquire schedules I and II controlled substances to the extent authorized by your issued 2007 procurement quotas.

Sincerely,

Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

cc: New Jersey Diversion Office